AUG 1 7 2001

K003552

ATTACHMENT 8 - 510(k) Summary

1. **Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)
Reservoir Place
1601 Trapelo Road
Waltham, MA 02451
Telephone Number: 781-890-0001
Fax Number: 781-890-6464
Contact Person: Linda Jalbert, Director, Regulatory Affairs

2. **Name of the Device**

Trade Name:	ITI® Dental Implant System
Common Name:	Endosseous dental implants
Classification Name:	Endosseous dental implants 21 CFR 872.3640

3. **Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)**

ITI® dental implants (K983742)
FRIALIT - 2® 3.4 implant (K994376)
Steri-Oss Replace™ Tapered Implants (K980439)

4. **Description of the Device**

ITI solid screw implants have an external spiral screw thread and an anchorage surface that is grit blasted then acid etched (SLA surface) or titanium plasma-sprayed (TPS surface). The implants are composed of Grade 4 titanium, cold worked. The neck of the implant, intended to remain above the crest of the bone on implantation, is a smooth machined surface to allow for the attachment of epithelial tissue. The round, symmetrical neck flares at the coronal end, creating an optimal emergence profile. The shoulder of the implant is machined at a 45° angle to maximize prosthesis stability. The implant has an internal octagon into which the abutment is placed to serve as the base for the prosthetic reconstruction.

5. **Intended Use of the Device**

ITI® solid screw implants are intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges or overdentures in edentulous or partially edentulous patients.

6. **Basis for Substantial Equivalence**

The subject ITI® dental implants are substantially equivalent in intended use to currently marketed ITI® dental implants, the FRIALIT – 2® 3.4mm dental implant, and the Steri-Oss Replace dental implant.

The FRIALIT – 2® 3.4mm dental implant is intended for use in single tooth restoration, edentulous spans restored with multiple single teeth, freestanding bridges, and to retain overdentures. The FRIALIT implant can also be used after extraction for immediate implant placement, delayed implant placement or late implant placement. This is the identical intended use as the subject ITI implants.

The subject ITI® implants are identical in all respects to previously cleared ITI implants. There has been no change in material, surface treatment, design, or operating principle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Institut Straumann SA
Ms. Linda Jalbert
Director of Regulatory Affairs
Straumann USA
1601 Trapelo Road
Reservoir Place
Waltham, Massachusetts 02451

Re: K003552
Trade/Device Name: ITI Dental Implant System
Regulation Number: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: April 26, 2001
Received: April 27, 2001

Dear Mr. Jalbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003552

Indications for Use Statement

Device Name:

ITI® Dental Implant System

Indications for Use:

ITI® solid screw implants are intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. The standard loading protocol for the ITI® DENTAL IMPLANT SYSTEM should be utilized for ITI solid screw implants that are placed immediately.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003552